Comments to the Guidance draft

September 9th, 2004

1. Comment to Page 7, Framed flotation therapy products

The patients who are threaten with this kind of systems may are under sedative drugs mainly, but the risk is given and have to be valued. The valuation has to be done with manufacturer at least. So it should not be taken out of the scope.

2. Comment to Page 15, Reduction of the measurement in zone 2 from 120mm to 60mm

The recommendation should stay with the measurement of 120mm because:

- The measurement as IEC mentioned (without mattress) covers the worst case, because the zone is at maximum size and the mattress will reduce the open area.
- The measurement will be reduced by moving the mattress support platform when the side rail is not mounted to the mattress support platform, so no additional hazard will be expected due to the movement.

3. Comment to page 16, Reduction of the measurement in zone 3 from 120mm to 60mm

The recommendation should be changed from 120mm to 60mm, because:

- The use of non-recommended mattresses is foreseeable misuse. By using 120mm as an acceptable space between mattress and side rail, the likelihood of a space more than 120 is high.
- Adjusting a width of 60mm can reduce the possibility of an enlargement of the space to a non-acceptable measurement by compression or movement of the mattress.

4. Comment to page 20, Recommendation for zone 5

The FDA should stay with the recommendation, because the hazard for neck and chest entrapment exists and have to taken under consideration. This kind of recommendation supports manufacturers to develop safe products, because not always well-experience technicians (in terms of non-technical issues) are commissioned to develop side rails.

5. Comment to page 21, Recommendation for zone 6

The FDA should stay with the recommendation to the zone 6, because the hazard for neck and chest entrapment exists and have to taken under consideration. This kind of recommendation supports manufacturers to develop safe products, because not always well-experience technicians (in terms of non-technical issues) are commissioned to develop side rails.

The recommendation should be given for head and foot end side, because confused and/or restless patient could moving around in the bed and entrapment can also happen at foot end.

6. Comment to page 22, Recommendation for zone 7

The FDA should recommend a measurement for zone 7 because the same hazard as in zone 3 is given and cannot be handled in another way.

7. Comment to page 23, Measurements of angled position

My believe is, that entrapment can happen in flat and articulated position, but

- It depends on the construction of the side rails whether the hazard increase or decrease due to the articulated position
- The accessibility of the gaps in articulated position has to considered
- The main use of side rails is for prevent falls during night and the most people sleep in flat position
- Articulated position used often in intensive care and this patient are under sedative drugs mainly.

Because of the situation that the possible entrapment zones are strongly depending on the construction of the side rails, the measurements mentioned on page 24 should be also allocated to hazards and not to zones only. That means when the entrapment of neck could be expected, the width of the opening has to be less than 60mm and an angle more than 60° degrees, in case of head less than 120mm, in case of chest more than 318mm.

8. Comment to page 23, Application of the guidance

I see no reason for differentiation between the intended use areas.

General comments:

The draft should refer to the IEC601-2-38 regarding the forces applicable to confirm the measurements.